

ORIGINAL

COMMONWEALTH OF KENTUCKY
DEPARTMENT FOR MEDICAID SERVICES

TRANSCRIPT
OF
DRUG MANAGEMENT REVIEW ADVISORY BOARD MEETING

August 29, 2001
1:30 P.M.
Room 125, Capitol Annex
Frankfort, Kentucky 40601

MEMBERS PRESENT

Robert Hughes, M.D.
CHAIRMAN

Phillip Baier, O.D.
George Rodgers, M.D.
Richard W. Arnold, M.D.
Patricia Freeman, R.Ph. Ph.D.
Melody Ryan, Pharm. D.
Janet Poe Wright, Pharm. D.
Danna E. Droz
(Proxy for James Davis, M.D.)

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1 later to get the second one filled.

2 CHAIRMAN HUGHES:

3 We actually addressed that issue. There were
4 some three-day prescriptions written and then shortly
5 behind that something else followed. Any other
6 questions from the Board on that? Okay.

7 The Purdue Pharmaceutical Company had requested
8 five to ten minutes to discuss, I believe, pain
9 management and the Oxycontin issue.

10 MR. CONNALE:

11 On behalf of Dr. Hughes and the DMRAB
12 Committee, I would like to thank you for the five to
13 ten minutes that we will be addressing a couple of
14 ideas this afternoon.

15 I'm Kevin Connale. I'm the Account Executive
16 in the Managed Care Division out of Cornelius, North
17 Carolina. And to my right is Dr. Ruth Plant, our
18 Medical Liaison, who she and I both cover Kentucky
19 covering the Medical Board, Pharmacy Board, Pharmacy
20 Association, Medical Association, and Medicaid.

21 In the next few minutes, I'd like to introduce
22 to you some things that we are currently doing in the
23 State of Kentucky and have been doing and also some
24 examples that we have actually done and worked with the
25 State of Mississippi with their Medicaid Drug

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1 Utilization Review Committee to mail to physicians
2 within the State of Mississippi.

3 Before I get started, I wanted to let you know
4 some of the materials that are currently going out in
5 the community are not part of your packet. If you
6 would like any of these additional copies, I could get
7 those to you. But I wanted to let you know what I
8 thought would be most appropriate for physicians within
9 your network within the State of Kentucky.

10 One of the very popular components right now is
11 an opioid therapy documentation kit that's on a CD rom.
12 This is something that can actually be ordered in
13 through a VCR card that we could actually put into a
14 packet such as the one in front of you.

15 The Pharmacy Board and Pharmacy Association
16 have just, as of this morning, have supported the anti-
17 diversion brochure that will be going out to every
18 pharmacist in the State of Kentucky. And the Kentucky
19 Board of Pharmacy has also sent out two CE's. These
20 are CE's that are two hours for physicians,
21 pharmacists, nurses, and case managers. The first that
22 went out this past spring was called the Use of Opioids
23 in Chronic Non-Cancer Pain. The one that will be going
24 out in the next month is called The Impact of Chronic
25 Pain and Interdisciplinary Perspective.

1 Inside your folders, though, I've included some
2 pieces that have not gone out to give these value
3 added. And the reason that I'm here today is we know
4 that education is the key when it comes to health care
5 professionals dealing with a disease state such as
6 pain management. And, so, I chose two of the pieces
7 that Mississippi Medicaid decided to mail, but I also
8 included five other pieces that have been extremely
9 popular for the various organizations that Dr. Plant
10 and I have called on.

11 The first is a zero to ten pain scale. This is
12 exactly what is being used more and more because of the
13 Joint Commission standards for pain as a fifth vital
14 sign. And, so, this is one of the first steps of
15 treating pain within one's office, long-term-care
16 facility, hospital, etcetera.

17 One of the other materials that actually went
18 out through the Medical Association for the State of
19 Alabama, MASA, was How to Stop Drug Diversion and
20 Protect Your Practice. This would be a nice reference
21 to use for physicians within his or her own practice on
22 how to treat pain for the legitimate patient but keep
23 an eye out for those who may not be legitimate.

24 The third piece is one that is a managed care
25 piece which is my department and that's called

1 Principles of Highly Effective Pain Managers, and it
2 really discusses the impact of pain as a fifth vital
3 sign and how to appropriately treat pain on a daily
4 basis.

5 One of the other materials is a joint statement
6 that came out back in 1997 from the American Academy of
7 Pain Medicine and the American Pain Society of the use
8 of opioids for chronic non-cancer pain, and this
9 basically is a statement referenced by these two
10 influential organizations.

11 One of the other pieces that just recently came
12 out is a joint statement from the American Pain
13 Society, the American Academy of Pain Medicine, and the
14 American Society of Addiction Medicine, and these are
15 common definitions used in the treatment of pain --
16 addiction versus pseudo-addiction, tolerance versus
17 pseudo-tolerance. So, these are one of the joint
18 statements that just recently came out to accompany the
19 other brochure I just referenced.

20 One of the interim directors for the American
21 Academy of Pain Management is Dr. Barry Cole who put
22 together Clinical Practice: Ten Tips to Survive Opioid
23 Prescribing, and this is something that is really short
24 and sweet. It's really helpful for physicians when he
25 or she might be prescribing an opioid.

1 Also in your packet is a CE that has not gone
2 out to any physicians, pharmacists nurses, or case
3 managers in the State of Kentucky, and that is one
4 called The Cost of Pain. This is one that each one of
5 you can order to review for your own as well as benefit
6 from the CE's, and Dr. Barry Cole was the writer of
7 this particular CE. And this would give a value-added
8 service to physicians within the State of Kentucky that
9 would not have received this CE so far.

10 And, lastly, part of the opioid therapy
11 documentation kit, this, along with the Ten Tips to
12 Opioid Prescribing, these were the two pieces that the
13 State of Mississippi approved through the DUR Committee
14 to mail out to physicians within the State of
15 Mississippi. And the Purdue logo is not on the Ten
16 Tips to Prescribing but is on the Pain Agreement.

17 The Pain Agreement is probably one of the most
18 beneficial tools that health care professionals can
19 receive, and that is basically having a patient agree
20 to one physician and one pharmacy and having the
21 patient choose the pharmacy he or she would like to
22 use.

23 But by mailing these out, the Purdue logo can
24 be removed, and that was an issue with the State of
25 Mississippi. This logo was taken off and these two

pieces were mailed out with a letter from the State of Mississippi Medicaid.

So, I wanted you to have these folders to review, and all of these materials can be mailed out at one time. You could choose just one. You can choose two. But I wanted to let you know of the third-party materials that are available to help treat a painful, legitimate patient and this is something I wanted you to have a chance to have.

DR. PLANT:

In addition to these efforts, we've been working with the Medical Board as well and we're assisting them in mailing out the new Kentucky Medical Board guidelines for the appropriate use of opioids in treating intractable pain. And those should be going out within the next couple of weeks to all the physicians within the state.

So, we felt that this educational effort might be a nice complement to follow up the guidelines to help educate physicians. We know physicians and pharmacists traditionally, to this date anyway, don't get a lot of pain management education in school. And if we can help supply third-party, nonprofessional pieces that might help with that educational process, that's why we're coming to you all to see if you'd like

1 to work with us with a mailing.

2 CHAIRMAN HUGHES:

3 Let me just make one comment. Pain management
4 is a part of every training because you take care of
5 people with terminal cancer and there's an appropriate
6 way to do that. So, on that one point, I would
7 disagree. There is appropriate training that's been
8 received.

9 But there are some things in here that appear
10 to be worthy. This Pain Management Agreement looks to
11 be pretty good because you've got the person's
12 signature there to agree to abide by those rules. And
13 if you abide by those rules, the chance of the person
14 abusing the system, so to speak, is much less. So,
15 that's a good piece.

16 But, again, I would just disagree on the fact
17 that pharmacists and physicians have not had training
18 in pain management. They treat thousands of people
19 with pain.

20 DR. PLANT:

21 I'm basing that on some of the studies where physicians
22 have been surveyed. Fifty-three percent of oncologists
23 surveyed considered their training to be poor. I'm
24 basing it on surveys such as that. So, maybe there was
25 training but maybe they felt it was inadequate to meet

1 some of their needs.

2 CHAIRMAN HUGHES:

3 But I don't know how you could improve upon that other
4 than the physician seeing that the patient is in pain
5 or the patient expresses pain and, therefore, they
6 relieve the pain and they follow that up with a
7 question, are you relieved. I mean, how better can you
8 improve upon that?

9 DR. PLANT:

10 That's true. The nice thing about the CD
11 documentation kit, and as Kevin pointed out, we could
12 put in a little card if physicians would like this, we
13 can send it to them, is that that opioid agreement is
14 on here, but there's also assessment tools on here,
15 initial and ongoing assessment tools, and these are
16 just templates. So, if a physician, for instance, had
17 the agreement, Dr. Hughes, and said, gee, I'd like to
18 add something to that, they could do that. This just
19 simply acts as a template.

20 So, if you're interested in using the
21 agreement, you might want to consider also a VCR card
22 that would allow them to order this as it gives more
23 tools and it's a template, so, if they want to adjust
24 it to their practice setting, that would enable them to
25 do that. And we can leave this copy with you all and

1 you're more than welcome to play with it and look at
2 it.

3 CHAIRMAN HUGHES:

4 Thank you. Any questions from the Board? Dr. Rodgers.

5 DR. RODGERS:

6 I do have a couple of comments actually. This
7 one I think I tend to disagree with Dr. Hughes a little
8 bit. My question is that the major routes by which
9 this stuff is being diverted are not going to be
10 affected by that sort of an agreement because it's not
11 the little old lady who is getting this inappropriately
12 for arthritis pain.

13 I think the diversion is coming from other
14 sources. Reading the local newspaper in this area
15 leads me to believe that both you all and other states
16 are looking at other mechanisms by which the
17 distribution and prevention and diversion need to be
18 undertaken.

19 I'm a pessimist when it comes to physician
20 education even though I'm a physician. I don't argue
21 that we shouldn't try it, but I'm not very optimistic
22 that it's going to make big changes. And particularly
23 I'm not very optimistic that it's going to make big
24 changes in the area of narcotic diversion because the
25 people who are doing that know what they're doing.

1 They're not doing it because they're uneducated, by and
2 large.

3 And I'm curious if you would share with us some
4 of the other alternative approaches that perhaps
5 Kentucky ought to be thinking about along with other
6 states that are facing this same problem.

7 DR. PLANT:

8 By other approaches, could you be more specific?

9 DR. RODGERS:

10 Control on distribution, other controls on
11 distribution. Some of your northeastern states are
12 looking at legislative ways of doing that. My
13 understanding was that Purdue as a corporation was
14 cooperating in some of those attempts. Would you care
15 to discuss those?

16 DR. PLANT:

17 Well, we're actually involved, as you've
18 probably read, in the State of Virginia with them in
19 developing a pilot. You all have been very fortunate
20 to have the KASPER system here. Very few states to
21 this point have had any form of a monitoring system.
22 And, so, we're trying to help develop what would be the
23 ideal monitoring system, a tool that maybe physicians
24 could use at the point of seeing the patient as opposed
25 to something more retrospective. So, that's one area

1 we're working.

2 Obviously, diversion can happen and abuse and
3 misuse can happen from a multitude of angles. In
4 Kentucky, you all have your tamper-resistant
5 prescriptions, but in other states they have not. So,
6 we've worked with that.

7 You mentioned that you didn't feel oploid
8 agreements were necessarily 100% effective and they're
9 not. But what I found with speaking with physicians is
10 they don't want to be confrontational with their
11 patients. They want to believe their patients and
12 we're told we should believe our patients with regards
13 to pain. But this gives a physician who is trying to
14 do the right thing a mechanism to outline the patient's
15 responsibilities and the physician's responsibilities.
16 And if the patient, in fact, breaks those
17 responsibilities, it gives them a mechanism to cut that
18 patient loose in a very non-confrontational black-and-
19 white way.

20 So, there are physicians that I do think that
21 this agreement is helpful. So, I don't know if that
22 answers your question.

23 DR. RODGERS:

24 I think there are really two issues. There are generic
25 issues with narcotics. I don't necessarily mean to

1 pick on you guys, but you're sitting there.

2 DR. PLANT;

3 That's all right.

4 DR. RODGERS:

5 One is appropriate use and I think you've
6 addressed that with some of the materials relative to
7 pain management, and I think that's good. The other is
8 the diversion issue which you guys have taken the
9 short, so to speak, in the last year as a particular
10 drug entity.

11 In addition to being a practicing physician, I
12 also run the Poison Center in this state, and I can
13 tell you that we don't get Oxycontin overdoses that are
14 accidental in people who are taking the drug
15 appropriately and all of a sudden something happens.
16 The people we get are the people who are getting this
17 drug through either illicit means or abuse or are
18 getting it through illicit means for overdose,
19 intentional overdose, and it is a problem. There are a
20 slew of them, a disproportionate slew of them, and I
21 don't really think we need to talk about that.

22 But I think that the tools in here are directed
23 primarily at the former, which is appropriate use for
24 people who perhaps need narcotics and both educating
25 the patient and working with the physician for perhaps

1 better ways of minimizing that or using it
2 appropriately. That's fine.

3 But I think to get at the other which has been
4 the one that's attracted all the attention in this
5 state for some appropriate reasons, I think we need to
6 think out of this box. We're going to have to think
7 out of this box.

8 DR. PLANT:

9 Again, hopefully, things like the ten tips and the
10 anti-diversion brochures will put some concepts into
11 physicians' minds as far as documentation and ongoing
12 monitoring of their patients.

13 MR. CONNALE:

14 And one footnote on that. You brought up a
15 good point, Dr. Rodgers, and that is what can be done.
16 I have actually offered and had implemented two
17 educational programs for program integrity for the
18 State of Mississippi and for Tennessee. And both
19 programs were very well received on why are you seeing
20 an increase in opioids. Who is appropriate. Who may
21 not be.

22 But the one follow-up I have had with Tennessee
23 was the pain agreement, and that's something that some
24 physicians are using. Some are starting to use it
25 more. But that is one way of finding out who is drug-

1 seeking, who is having drug-seeking behavior.

2 So, what Dr. Hughes was alluding to is that's a
3 nice, as Ruth also mentioned, is a nice first step
4 because that has sort of helped with that concept of
5 making sure people that are legitimate---

6 CHAIRMAN HUGHES:

7 Let me just say one thing. The agreement is not a
8 cure-all, like Dr. Rodgers said. And the agreement, as
9 you picked up on, is a way to hopefully reduce some
10 confrontation and also it establishes an automatic
11 mechanism for cutting that patient off if they're drug-
12 seeking with one violation.

13 But the other thing, too, and this is just a
14 thought on the KASPER report. If someone comes in and
15 they want something that you have the least index of
16 suspension on, just get a KASPER report, but ask the
17 first question, is there anyone else writing those
18 controlled substances, and frequently you'll get the
19 answer, no. Run the KASPER report and right there
20 you've got your violation of the---

21 DR. RODGERS:

22 I think we get it from the point of view of who
23 is prescribing and who is using. The other issue that
24 has hit the press this week, as you're probably aware,
25 not with Purdue Frederick but with one of your

1 colleagues in the pharmaceutical industry, is the
2 responsibility of the company when they realize that
3 there is a distribution problem. This relates to the
4 issue in Arkansas.

5 But I think the same thing potentially could
6 relate to suppliers of narcotics. If you know that
7 you're shipping three truckloads of this stuff a month
8 to the pharmacy in Paintsville, I mean, what's the
9 obligation to let us know that this stuff is going in
10 the back door in truckloads and it's going out the
11 front door somehow? I don't know the answer to that.

12 DR. PLANT:

13 Obviously, we can't comment on that because---

14 DR. RODGERS:

15 The question was raised this week and it's going to be
16 raised in a courtroom and we'll see what the
17 liabilities are.

18 DR. PLANT:

19 Well, again, I think any manufacturer is obligated to
20 make sure that they are providing appropriate education
21 for the appropriate use of their products, and that's
22 what we're here to try to do. So, hopefully, we'll
23 strike up some interest from you all and maybe do a
24 cooperative mailing with any of the pieces you find
25 interesting.

1 CHAIRMAN HUGHES:

2 Any other questions? Steve.

3 MR. HILL:

4 I just wanted to comment on Dr. Rodgers' comment about
5 the distribution. That is in place now. The DEA
6 routinely monitors at the wholesale level where those
7 drugs go, whether it's two, three or four. And
8 anyplace that has outside of the norm gets an audit.
9 I've actually had one on a cough syrup one time because
10 all the physicians started on this one particular
11 hydrocodone cough syrup and they said, well, you're
12 using too much. Well, everybody down here likes it.
13 But that does happen and it is there.

14 CHAIRMAN HUGHES:

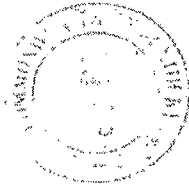
15 Any further comments? Thank you. Under New Business,
16 the Senate Bill 351 and House Bill 608 drug reviews, I
17 believe Cliff and Dr. Moore were going to present that.

18 DR. MOORE:

19 Yes. In accordance with KRS 205-5631 through 34, we
20 are continuing to do the new drug reviews and the
21 comparable drug reviews. We have two that we have
22 received from the UK Special Unit for a presentation to
23 the Committee today.

24 PROFESSOR HYNINMAN:

25 These two reviews both have some issues in



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September 17, 2001

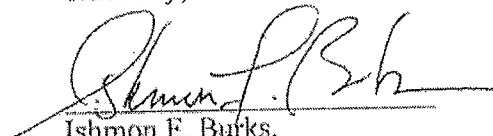
Governor's Oxycontin/Prescription Drug Abuse Task Force Members:

On Tuesday, September 18, 2001, at 1000 hours, I will be presenting the results and recommendations of the task force to the Judiciary Committee of the Kentucky General Assembly. I would like to extend my personal invitation for you to attend this hearing, located in Room 149 of the Capital Annex.

I have enclosed a copy of the interim OxyContin Task Force Report for your review. You will be notified of a follow-up meeting regarding this report and the results of the presentation to the Judiciary Committee.

If you have any questions, please contact me at 502-695-6300.

Sincerely,


Ishmon F. Burks,
Commissioner

IFB/lmr

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SEP 18 2001

J. DAVID HADDOX, DDS, MD



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EXHIBIT 11

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